UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,649	03/09/2001	Richard W. Compans	25-01	6596

23713 7590 10/22/2003

GREENLEE WINNER AND SULLIVAN P C
5370 MANHATTAN CIRCLE
SUITE 201
BOULDER, CO 80303

EXAMINER	
BAHAR, MOJDEH	

ART UNIT	PAPER NUMBER
1617	19

DATE MAILED: 10/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/803,649	COMPANS ET AL.	
	Examiner	Art Unit	
	Mojdeh Bahar	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5 and 7-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5 and 7-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/22/03 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 5, 7-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glenn et al. (USPN 5,980,898) in view of Fields et al.

Glenn et al. (USPN 5,980,898) teaches a transcutaneous immunization formulation comprising antigen and an adjuvant applied to unbroken skin and without perforation of the skin induces an immune response, see abstract particularly. Glenn et al. (USPN 5,980,898) further teaches that the antigen may be derived from a virus or from a membrane alone, see col. 3, lines 64-65, col. 5, lines 8-20. Glenn et al. also teaches that an antigen may be in the form of an inactivated virus, see col. 4, lines 11-12. Among the viruses that can be used in the practice of the invention Glenn teaches hepatitis, influenza, measles and vaccinia, see particularly col. 9,

line 13-24. Glenn et al. also teaches Hemophilus influenza B conjugate and Hepatitis as antigens that were used for immunization, see col. 8, line 55-65 and col. 16, lines 48-61.

Glenn et al. (USPN 5,980,898) does not teach the method of inactivating the viruses, neither does it teach the size of the antigenic particles in nm. Nor does it teach that the particulate antigen comprises hemogglutinin.

Fields et al. teaches that hemoggltinin (HA) is the major antigen of influenza virus, a known orthomyxovirus, see page 1417-1418. Fields also teaches that semipurified influenza virus subunit vaccines containing the HA surface antigens of the virus are less toxic than are activated whole virus vaccines, see page 475. Fields also teaches a method of inactivating viruses employing formalin, see page 475.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to inactivate the viruses by any of the widely known methods in the art. It would have also been obvious to employ the antigenic particles in sizes recited herein.

One of ordinary skill in the art would have been motivated to employ any of the viruses taught in Glenn et al. in a transcutaneous immunization formulation because they are known to be useful in transcutaneous formulations used to induce an immune response. Furthermore the different methods of inactivating viruses is within the purview of the Skilled Artisan. As to the particle size, note that the claimed particle size must include non-intact virus.

Response to Arguments

Applicant's arguments filed on August 22, 2003 have been fully considered but they are not persuasive. Applicant first argues that Glenn does not suggest the use of an antigen without

cholera toxin. Note that Glenn teaches adjuvants other than cholera toxin, see Examples 13-15 or claim 11 listing other adjuvants, for example. Applicant argues that soluble proteins as antigens were used in the prior art reference. Note that the instant claims do not exclude soluble proteins.

Applicant then argues that the listing of viruses in col. 9 of the prior art reference, cited in the previous office action is to provide a list of infectious pathogens against which the soluble proteins can be used. Note that the prior art reference states: "Plotkin and Mortimer provide antigens which can be used to vaccinate animals or humans to induce an immune response specific for particular pathogens, as well as methods of preparing antigen, determining a suitable dose of antigen, assaying for induction of an immune response , and treating infection by a pathogen (e.g., bacterium, virus, fungus or parasite)," see col. Lin 66-col.9 line 5.

The prior art reference then lists the viruses: teaches hepatitis, influenza, measles and vaccinia, see particularly col. 9, line 13-24. This passage seems to provide a list of pathogens, including viruses that can be used in the preparation of antigens as well as treatment of infections resulting from the pathogens.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from Monday, Tuesday, Thursday and Friday from 8:30 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

M. Bahar 10/17/03

Mojdeh Bahar
Patent Examiner
October 20, 2003